IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: William J. Curatolo, et al.

SERIAL NO.: 09/745,095

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FOR: Hydrogel-Driven Drug Dosage Form

Examiner: S. Gollamudi
Art Unit: 1616

#13
A Harm
1/16/03

Commissioner for Patents
Washington, D.C. 20231

Sir:

DECLARATION UNDER 37 CFR 1.132

I, Scott B. McCray, declare that:

1. I was awarded the degree of Bachelor of Science in Chemical Engineering in 1979 by the University of California-Los Angeles, a degree of Master of Science in Chemical Engineering in 1981 by the University of California-Los Angeles, and subsequently awarded a Ph.D. in Chemical Engineering in 1984 by the University of California-Los Angeles. I have been employed by Bend Research, Inc., of which I am also part owner, up to the present time. My title is Director of Membrane Development.

2. Bend Research, Inc. is part-owned by Pfizer, Inc., the Assignee of the above-identified application.

3. I am familiar with the instant patent application. I have read the Office Action which was mailed July 2, 2002, and am aware of the rejection of claims 2, 7-9, 12-32, 44-45, 49-51, 56-67, 63-81, 88-97, 101, 103-108, 118-122, 124, and 130-131 over US patent 5,620,705 (hereinafter "Dong") as set forth therein.

4. Under my direction, and as described in the Experimental Protocol attached hereto, three compacts of a water-swellable composition were prepared according to the Experimental Protocol, which forms a part of this Declaration and is incorporated by reference herein.

5. The object of the preparation of the compacts was to determine whether the water-swellable composition of Dong had the swelling ratio required by claim 2 of the instant patent application.

6. Three compacts were prepared as described in the attached Experimental Protocol. The materials and relative amounts used to form the compacts were the same as those described for the displacement layer in Example 7 of Dong. Compacts containing 500 mg of the material were formed using a 13/32" die (rather than the 17/64" die of Dong) in order to allow a comparison to the water-swellable compositions described in Example 12 of the instant application. Since Dong did not describe a compression force in Example 7, the compact was compressed to yield a compact having a strength of 6.0 Kp/cm^2. This was chosen to allow a comparison to the water-swellable compositions described in

Example 12 of the instant application, which had strengths ranging from 3 to 16 Kp/cm^2.

7. The swelling ratio of the so-formed compacts was measured using the same procedure for measuring swelling ratio described in Example 12 of the instant patent application. As shown in Table II of the Experimental Protocol, the average swelling ratio in deionized water for the three compacts prepared according to Example 7 of Dong was 2.4.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that theses statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Dec. 27, 2002
Date

Scott B. McCray
Scott B. McCray

EXPERIMENTAL PROTOCOL

Evaluation of Water Swellable Composition from U.S. 5,620,705

The water-swellable composition disclosed in Example 7 of U.S. Patent No. 5,620,705 was evaluated using the following procedure. First, 5.875 g sodium carboxymethylcellulose (CMC)(type 7H4F PH; Hercules Inc., Wilmington, DE), 3.00 g sodium chloride, 0.50 g hydroxypropyl methyl cellulose (HPMC)(Methocel E3 Prem LV; Dow Chemical Co., Midland, MI), and 0.10 g ferric oxide (Aldrich product no. 52,931-1) were combined and blended for 20 minutes in a Turbula mixer. Next, the mixture was wet granulated using a mortar and pestle, with 10.0 g of aqueous solution containing 5 wt% hydroxypropylcellulose (HPC)(Klucel EF; Hercules Inc.). The granules were dried overnight in a Gruenberg tray drier at 40°C, sieved through a no. 6 mesh screen, and 0.025 g of magnesium stearate was added. Table I summarizes the ingredients used in the formation of this water-swellable composition.

Table I

Ingredient	Amount Used (g)	Amount (wt%)*	From Example 7 of U.S. Patent 5,620,705 (wt%)
Sodium CMC	5.875	58.75	58.75
Sodium chloride	3.00	30.0	30.0
HPMC	0.50	5.0	5.0
Ferric oxide	0.10	1.0	1.0
HPC	0.50	5.0	5.0
Water*	9.50	--	--
Magnesium stearate	0.025	0.25	0.25
Total	10.00	100.00	100.00
* Water was not present in the final granulation			

Compacts of the water-swellable composition were formed by placing 500 mg of the composition in a standard 13/32" die and compressing using an f press. An average strength of 6.0 Kp/cm^2 was measured using a Schleuniger Tablet Hardness Tester, model 6D.

The swelling ratio of the above compacts was determined using the following procedure. A compact was placed into a glass tube with a diameter slightly larger than the compact. The compact resided on a stationary frit equilibrated with

deionized water at 37°C. A moveable frit was placed on top of the compact and the height of the compact above the stationary frit marked. The tube was then placed into a reservoir containing deionized water at 37°C such that the stationary frit was in contact with the water. Over time, the compact swelled as water contacted the compact. The height of the moveable frit was measured over time. From the ratio of the height after 21 hours of equilibration in deionized water and the initial height, the swelling ratio of the compact was determined. The results of these tests, performed in triplicate, are summarized in Table II.

Table II.

Compact Sample	Swelling Ratio
Compact No. 1	2.3
Compact No. 2	2.5
Compact No. 3	2.4
Average	2.4 ± 0.1